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Lucia A Keegan 03/06/2007 09:56:11 AM From DB/Inbox: Lucia A Keegan

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¶1. (SBU) Summary: Following PhRMA's nomination of France for the 2007 Watch List, Embassy officers have met with two of France's major interlocutors in the pharmaceutical sector: the French Pharmaceutical Companies Association LEEM, and the Price Negotiating Committee (CEPS) for reimbursable drugs. Both industry and government representatives expect shorter timelines for the pricing and reimbursement approval process as a result of a recent annex to a 2003 GOF-Industry Framework Agreement. They further note that, under pressure from industry, the 1.76 percent tax on pharmaceuticals was scaled back to 1 percent and that possible further reduction in the tax may be part of new incentives for innovative companies. End of Summary

The Key French interlocutors

¶2. (SBU) During the week of February 26, Embassy Econ and FCS officers met with representatives of two of France's major players in the pharmaceutical sector: Beatrice Kressmann, Director for European and International Affairs of the French Pharmaceutical Industries Association (LEEM), whose 330 members (60 percent of which are U.S., Japanese and non-French EU companies operating in France) account for 97 percent of total sales revenues of pharmaceutical products for human use in France; and Noel Renaudin, President of the Health Products Economic Commission (CEPS), which consists of government representatives from the ministries of health and industry as well as health insurance companies.

Speeding up market access of innovative products

¶3. (SBU) In January 2007 LEEM and CEPS signed an annex to the Framework Agreement that has governed their relations since 2003. This annex will allow a larger number of innovative products to benefit from a faster price approval mechanism under the 2003 French Social Security Finance Bill. LEEM's Kressmann said the annex also improves the environment for industry/government dialogue on a range of pricing and related issues, including on the potential introduction of generics onto the market.

¶4. (SBU) In France the price for a product is based on a price proposal by the company and an "ASMR" level, assigned by a Transparency Commission to reflect the level of the given product's innovation. The Transparency Commission consists of industry representatives, independent experts and health officials. The ASMR is determined by using three reference products sold in France: the most prescribed product; the least expensive product, and the product most recently listed on the reimbursed list. The decision on the ASMR level has a direct impact on the price the company will be able to receive for its product. ASMR category I drugs (the most innovative) essentially receive prices determined by producers, while category IV drugs (the least innovative) are allowed onto the market, but at the price of the drug's closest competitor.

¶5. (SBU) The final price is established following discussions between the company and the CEPS on the basis of elements such as the size of the target population and the number of prescriptions for the condition or disease. The 2003 Social Security Finance Bill introduced some flexibility by providing that a company's price proposal is automatically accepted unless challenged by the CEPS within 75 days of the decision by the Transparency Commission. The CEPS' Renaudin said as long as companies respect the rules of the game -- including price proposals that fall within the range of prices elsewhere in the EU, and a willingness to practice full disclosure on issues that might impact price -- declaratory pricing is the rule rather than the exception. This procedure, which previously applied to the more innovative products (ASMR I, II and III), has now been extended to ASMR IV products. According to LEEM's Kressmann, improvements in the price notification procedures, including those introduced in the recently-negotiated Framework Agreement Annex, will have a "very major positive impact" on industry.

¶6. (SBU) The CEPS' Renaudin says that France's approach to containing pharmaceutical costs revolves around three principles. First, the approach to innovation in the ASMR process has become somewhat more selective. Renaudin says this is not an explicit cost containment policy (budget officials are not a part of Transparency Committee deliberations), but reflects a general consensus that true innovation should be awarded the top ASMR ratings, while drugs that provide at best marginal improvements should not. Second, for older products (five years minimum) the Committee exercises pressure on pricing. Third, there is an active policy to encourage generics. If patients wish to use a name brand drug, they may pay pharmacists directly and receive reimbursement later. But for those willing to use generics, no initial outlays are required.

Promoting Innovation

¶7. (SBU) Following a meeting of the Strategic Health Industries Council (CSIS) in February, Health and Industry Ministers Xavier Bertrand and Frangois Loos announced a pledge by the GOF and the pharmaceutical industry to increase spending on medical research and development by 10 percent over the next three years. With the new target, the Ministers have stated that France's pharmaceutical industry could rival that of the UK in terms of money invested in research and development. Currently the pharmaceutical industry in France spends 12 percent of revenue on research and development, compared to an average of 15 to 20 percent elsewhere.

Remaining Concerns

¶8. (SBU) LEEM's Kressmann highlights that negotiated price cuts have not affected the most innovative products (ASMR I, II and III), which remain at an EU price level. While LEEM regards the February 5 meeting of the Strategic Health Industries Council as positive for research and development in the pharmaceutical industry, it remains

concerned about the industry's low growth rate of 1.5 percent in 2006 -- expected to remain depressed through 2008 -- and the negative impact that will have on employment and French competitiveness. Kressmann also complains about the 1 percent pharmaceutical tax, though she notes that the rate has come down from 1.6 percent. GOF preference for generics (as outlined para 6) is equally problematic for the industry, she says. Generics "must come at their appropriate time" and French generic policy encouragement does not represent "free and fair" competition.

¶9. (SBU) But Kressmann said industry's main concern was over inconsistency in recent GOF policy on pharmaceuticals. In order to plan ahead the industry required a more stable policy environment - notably on taxes and spending decisions -- than what it had experienced over the past several years. That said, she thought many of the policy shifts were an aberration due to one-off efforts to reign in unsustainable deficit growth in French Social Security spending. Her comments were partially echoed by the CEPS' Renaudin, who thought targeted pharmaceutical spending growth limits of one percent per annum were unsustainable, and that beginning next year spending growth would likely increase to levels slightly above GDP growth. Kressmann concluded that from a policy view it is "difficult to say that (what the GOF is doing) is not fair, that it can't limit expenses." Nevertheless she says the industry continues to argue its position, and is hopeful that it will get back to a more robust growth environment in the next two years.

Stapleton